THE LIFE SCIENCES LAW REVIEW

SEVENTH EDITION

Editor
Richard Kingham

THE LAWREVIEWS

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PREFACE

The seventh edition of *The Life Sciences Law Review* covers a total of 34 jurisdictions, providing an overview of legal requirements of interest to pharmaceutical, biotechnology and medical device companies. The chapters are arranged so as to describe requirements throughout the life cycle of a regulated product, from discovery to clinical trials, the marketing authorisation process and post-approval controls. Certain other legal matters of special interest to manufacturers of medical products – including administrative remedies, pricing and reimbursement, competition law, special liability regimes and commercial transactions – are also covered. Finally, there is a special chapter on international harmonisation, which is of increasing importance in many of the regulatory systems that are described in the national chapters.

The past year has seen a number of significant developments. After many years of negotiations and false starts, the United States and EU have finally begun to implement a programme of mutual recognition of inspections of drug manufacturing establishments, thus simplifying the shipment of drug products between the jurisdictions and freeing resources to carry out more inspections in third countries. In the meantime, the United States continues to debate whether to repeal the comprehensive medical care legislation enacted during the Obama administration, and is now considering measures to improve the transparency of pricing for prescription drugs. The United Kingdom is addressing changes to drug regulatory systems that must accompany the country's planned withdrawal from the EU, and drug and device manufacturers are actively planning for the effects of Brexit on their supply chains. The governments in India and China continue to consider changes in their regulatory systems for drugs and medical devices.

It is vitally important that lawyers who advise companies in the life sciences sector and the business executives whom they serve have a working knowledge of the regulations and policies that govern drugs, biologics and medical devices. It is equally important to keep up to date with developments in the regulatory systems, which govern access to the market, pricing and reimbursement, advertising and promotion, and numerous other matters that are essential to success. It is our hope that this annual publication will be helpful in this respect.

All of the chapters have been written by leading experts within the relevant jurisdiction. They are an impressive group, and it is a pleasure to be associated with them in the preparation of this publication.

Richard Kingham
Covington & Burling LLP
Washington, DC
March 2019

Chapter 21

PERU

María del Carmen Alvarado Bayo and Ricardo De Vettor Pinillos[1]

I INTRODUCTION

Law No. 29459 on Pharmaceutical Products, Medical Devices and Sanitary Products, enacted in November 2009, is the principal legislation that regulates pharmaceutical products, medical devices, sanitary products, pharmaceutical establishments (laboratories, storehouses, drugstores[2] and pharmacies) and activities related to the marketing, promotion, advertising and prescription of the aforementioned products.

This Law has been complemented with the issuance of several supreme decrees that regulate specific requirements and conditions for said products and activities, the most important of which are Supreme Decrees Nos. 16-2011-SA (Rules on the Registration, Control and Sanitary Surveillance of Pharmaceutical Products, Medical Devices and Sanitary Products) and 014-2011-SA (Rules for Pharmaceutical Establishments).

The General Directorate of Medicines, Supplies and Drugs (Digemid)[3] – a public entity that is part of the Ministry of Health – is the national competent authority in charge of granting all types of marketing authorisations regarding the above-mentioned products and their corresponding authorisations in order to carry out activities as pharmaceutical establishments. Digemid is also in charge of sanitary control and surveillance.

II THE REGULATORY REGIME

Law No. 29459 sets forth the conditions for granting marketing authorisations of pharmaceutical products, medical devices and sanitary products.

There are two principal authorisations for the manufacture and importation, and commercialisation and storage of pharmaceutical products and medical devices that can only be granted to individuals or companies duly incorporated in Peru: a health operating authorisation, which must be granted in order to carry out activities as a pharmaceutical establishment (laboratories, drugstores, warehouses and pharmacies); and a marketing authorisation of the product.

1 María del Carmen Alvarado Bayo is a partner and Ricardo De Vettor Pinillos is a senior associate at Rodrigo, Elías & Medrano Abogados.

2 'Drugstore' is defined as a pharmaceutical establishment dedicated to the import, export, trading, storing, quality control or distribution of pharmaceutical goods, medical devices or sanitary products.

3 La Dirección General de Medicamentos Insumos y Drogas (Digemid) was created by Legislative Decree No. 584 of 18 April 1990.

In this sense, medicines and medical devices manufactured locally or in a foreign country can only be traded with the corresponding marketing authorisation issued by Digemid to local companies.

i Classification

Law No. 29459 includes a subclassification of the products that are included under the following main categories:

a pharmaceutical products:
- medicines (which include pharmaceutical specialities, diagnostic agents, radiopharmaceuticals and medicinal gases). Pharmaceutical specialities are subclassified into specialities whose active pharmaceutical ingredient is: (1) included in the unique national list of essential medicines (Category 1); (2) not included in the unique national list of essential medicines but registered in high health surveillance countries[4] (Category 2); and (3) not included in categories 1 and 2 (Category 3);
- dietary and sugar substitutes;
- biological products;
- herbal medicines; and
- galenic products;

b medical devices of low, moderate, high or critical risk; and

c sanitary products (cosmetic, household cleaning and products for personal hygiene and protection).

Cosmetic and household cleaning products are regulated under the applicable international rules (Andean Decisions) for the member countries of the Andean Community (Bolivia, Colombia, Ecuador and Peru).

ii Non-clinical studies

Law No. 30407, enacted in January 2016, forbids any experiment and research involving living animals that may cause them unnecessary suffering, injury or death, unless the aforementioned is essential for study and scientific advances. The results of such experiments cannot be obtained through other procedures, or said procedures cannot be replaced by cell cultures or tissues, or computerised methods or videos, when such experiments are necessary for:

a the control, prevention, diagnosis or treatment of diseases affecting human beings or animals;

b the assessment, detection, regulation or modification of the physiological conditions in human beings and animals;

c the preservation of the environment and the maintenance of biodiversity;

d investigation of productive parameters in animals; and

e medical-legal research.

4 France, the Netherlands, the United Kingdom, the United States, Canada, Japan, Switzerland, Germany, Spain, Australia, Denmark, Italy, Norway, Belgium, Sweden, Republic of Korea, Portugal and Ireland.

The Institutional Research Ethics Committee for the Use of Animals, part of the National Health Institute (INS) within the Ministry of Health, is the national competent authority that approves investigation protocols involving animals. Since there are many gaps in the regulation of studies on animals, the second complementary transitory provision of Law No. 30407 indicated that within a term of 90 days counted from 8 January 2016, the Ministry of Health should issue an ethics code for the use of animals in research. However, no such code has yet been issued.

iii Clinical trials

Supreme Decree No. 021-2017-SA enacted in 30 June 2017 is the principle regulation regarding clinical trials, and the entity in charge of regulating and approving clinical trials is the INS.

Clinical trials must obtain prior authorisation issued by the General Office for Research and Technology Transfer, which is part of the INS. The authorisation can be requested by the sponsor or contracted research organisation and both need to be registered with the INS. The sponsor can be a foreign company but must have a legal representative in Peru duly empowered to act on its behalf with respect to any matter related to clinical trials.

It is only possible to request authorisations for clinical trials if the products under investigation comply with one or more of the following conditions:

a they have an authorisation for investigation in human beings issued by the corresponding drug authorities from high health surveillance countries;

b they are manufactured in Peru, have undergone preclinical investigation and are in accordance with the investigation policies or priorities determined by the Ministry of Health;

c they are used to establish therapeutic equivalence of pharmaceutical products or similarity of biological products;

d they are considered a priority for public health in Peru or part of the investigation policies or priorities determined by the Ministry of Health; and

e they need to have clinical trials, according to the Ministry of Health, to support their efficacy and safety in order to grant the marketing authorisation.

For the importation of products under investigation, it is mandatory to obtain a sanitary importation authorisation granted by Digemid. This authorisation can only be granted to companies duly incorporated in Peru and after the company has been granted the authorisation to conduct the clinical trial.

iv Named-patient and compassionate use procedures

Article 20 of Supreme Decree No. 016-2011-SA states that Digemid may provisionally authorise the importation and use of pharmaceutical products without sanitary registration or under conditions different from those ones stated in the sanitary registration for individual prevention or treatment. To obtain this authorisation, it is necessary to file an application submitting a medical report issued by a Peruvian doctor with a report stating the characteristics of the product.

The regulations state that the authorisation should be requested by the 'person with interest'; therefore, it should be the patient who performs the procedure. Nevertheless, the patient could delegate the rights to another person or entity to perform the procedure on his or her behalf.

v Pre-market clearance

The general rule is that all medicines and medical devices must be previously registered with Digemid for their commercialisation in the market and this is achieved by obtaining a marketing authorisation. The holder of the marketing authorisation is responsible for the quality of the product.

There are some exceptions to the general rule and in certain specific cases it is possible to manufacture, import or use pharmaceutical products and medical devices without a marketing authorisation as long as Digemid gives prior approval. Exceptions are only applicable for:

a use in urgent situations or if an emergency is declared;
b research and training purposes;
c prevention and individual treatment with the corresponding medical justification; and
d public health situations where the need and unavailability of the product in the national market is demonstrated.

vi Regulatory incentives

Patent legislation in Peru does not allow for granting extensions of patents and there are few incentives for the research and study of new chemical entities.

Marketing authorisations are independent of patent procedures and the two are not linked in any way.

Until 2009, there was no protection of test data submitted during the procedure for obtaining a marketing authorisation. This situation changed with the issuance of Legislative Decree No. 1072 on the protection of test data and other undisclosed data relating to pharmaceuticals, and now it is possible to protect undisclosed test data or other data on safety and efficacy for five years. The information that will be protected is related to the safety and efficacy of a pharmaceutical product containing a new chemical entity.

vii Post-approval controls

Digemid is legally authorised to permanently, and without prior notice, conduct technical inspections at pharmaceutical establishments as well as to monitor and perform tests of products to ensure their safety. These actions could result in cancellation of authorisations and even suspension of activities or closure of establishments.

The holder of a marketing authorisation of pharmaceutical products or medical devices should periodically submit security summaries (reports) in line with good pharmacovigilance practices according to the following agenda: (1) each six months during the first two years following the first commercialisation; (2) annually during the following three years, after the first two years have elapsed; and (3) every five years from the sixth year.

Likewise, before its commercialisation and distribution, the holder of the marketing authorisation must submit the results of the product's quality control for each and every batch. The quality control of the first batch that enters into the market, after registration of the product, must be conducted within the National Centre of Quality Control of the INS or in a laboratory duly authorised by Digemid.

viii Manufacturing controls

Manufacturing laboratories need to comply with good manufacturing, laboratory, storage, distribution and transportation practices, and must include independent areas

for manufacture, quality control and storage. Digemid conducts periodic supervisions to control the conditions and quality of the manufacturing processes as well as the quality of the products.

All manufacturing laboratories must function under the supervision of a technical director, who must be a qualified pharmaceutical chemist and who is in charge of the laboratory's manufacturing and quality control, among other responsibilities.

ix Advertising and promotion

Advertisements do not require authorisation or supervision before dissemination by any authority. The supervision and control takes place after the advertisement is released (ex-post control) and it is supervised by Peru's National Institute for the Defence of Competition and the Protection of Intellectual Property (Indecopi). The promotion and advertising of medicines and medical devices for sale with a medical prescription must be addressed exclusively to professionals who prescribe and dispense said products.

Advertising for non-prescription medicines must include legible and accurate information of the technical specifications. In the case of advertising panels and advertising on television, the information about the principal precautions and warnings must be clear, legible and perceptible to the public.

Samples must be duly labelled with all the technical and approved information included in the product's marketing authorisation and only physicians are allowed to directly provide samples to their patients.

x Distributors and wholesalers

Pursuant to Supreme Decree No. 014-2011-SA, all pharmaceutical establishments dedicated to the manufacture, importation, distribution, storage and commercialisation of medicines, medical devices and sanitary products, such as drugstores, warehouses and pharmacies, must necessarily obtain a health operating authorisation. Any of these establishments must appoint a permanent technical director or a pharmaceutical chemist (or both).

Laboratories and drugstores cannot commercialise pharmaceutical products or medical devices to end user consumers. Likewise, prescription medicines must only be sold in pharmacies, although some non-prescription medicines (with low sanitary risk) can be sold in commercial establishments (over-the-counter) as long as the establishment has been authorised by Digemid when granting the marketing authorisation for the product.

xi Classification of products

The general classification of products is outlined in Section II.i. Regarding pharmaceutical products (medicines), there is a subclassification depending on how the products will be dispensed. There are four subcategories that involve products that (1) require a specialised, numbered medical prescription; (2) require a simple medical prescription; (3) do not require a medical prescription but can only be sold in pharmacies; and (4) do not require a medical prescription and can be sold in commercial establishments.

A marketing authorisation will not be granted for a pharmaceutical product that has a commercial name that is identical or similar to another product already registered with a different formula. Likewise, a marketing authorisation will not be granted for a pharmaceutical product that has a trade name that corresponds to an international non-proprietary name (INN) or another term that could be confused with an INN.

xii Imports and exports

Besides the general information required by the customs authorities for the importation of pharmaceutical products, medical devices and sanitary products, it is necessary to provide the following:

a a copy of the resolution that authorises the marketing authorisation;
b identification of the shipment by the product's manufacturing batch and expiry date;
c an analysis certificate or protocol analysis conducted over the product's batch; and
d a good manufacturing practice (GMP) certificate granted by Digemid.

With regard to (d), it is possible to submit GMP certificates issued by competent authorities from high health surveillance countries or countries that have a mutual recognition with Peru. In August 2018, Supreme Decree No. 021-SA-2018 was enacted. It approved the GMP Manual applicable to local and foreign laboratories of pharmaceutical products (including products under investigation for clinical trials) and will enter into force in August 2019.

xiii Controlled substances

Narcotics and psychotropic drugs are subject to the control and supervision of Digemid. For the importation or exportation of said products, it is necessary to obtain an official certificate issued by Digemid.

The prescription of certain narcotics and psychotropic drugs must be undertaken in accordance with special numbered prescriptions that must comply with strict requirements related to the content of the drugs. Likewise, laboratories, importers and pharmacies must have a suitable record whenever substances or medicines that include narcotics or psychotropic drugs are dispensed.

xiv Enforcement

Digemid is duly empowered to adopt security measures, such as preventive retention, seizure, withdrawal or destruction of products or materials and equipment used. These measures can be executed without warning and are imposed regardless of other administrative sanctions that could also be applied, such as fines, cancellation of authorisations or closure of establishments.

Digemid promotes different campaigns to inform consumers about the dangers of falsified medicines and provide general recommendations to prevent the acquisition of said products.

Digemid constantly issues alerts to the national scientific community and to the public in general, with the objective of controlling and minimising the risk related to the sale of a certain product.

III PRICING AND REIMBURSEMENT

The Consumer Protection Commission has stated on several occasions that within a social market economy, price-fixing must be free, based on supply and demand, and that 'excessive' or 'exploitative' prices cannot be penalised. The only prices that may be fixed administratively are public services fees.

On the other hand, it has been stated that excessive prices generate incentives for other bidders (i.e., competitors with respect to whom exploitative conditions are imposed) to enter into the market and offer better prices. Therefore, the idea is that competitors should reduce prices to capture users' preferences.

In relation to drug prices, it has been stated that Peruvian legislation does not regulate the government's intervention in the price-fixing of drugs traded by private companies; however, the government has adopted different policies and measures with the purpose of helping to improve the access thereto by users of medicines.

IV ADMINISTRATIVE AND JUDICIAL REMEDIES

The procedures to obtain a health operating authorisation or marketing authorisation do not require the application to be published in a legal gazette or on Digemid's website. For this reason, it is very difficult for third parties to be aware of new applications. Even if the third parties obtain information about a product that might infringe patent rights, it would not be possible to oppose or impede registration as the law does not foresee a specific procedure for a third party to do so. The registration application is a two-party procedure (the applicant and the administration).

If an authorisation is rejected, the applicant can either file a writ of reconsideration or a writ of appeal against the decision. The reconsideration writ must be supported by new evidence and will be resolved by the same authority that issued the decision. The appeal is resolved by Digemid's general director, who acts as second and last administrative instance.

The decisions adopted by Digemid's general director acting as second instance can be challenged before the judiciary. For such purposes, it is necessary to file a lawsuit within a term of three months after the issuance of the final decision and the judicial case could reach up to three instances (a judge specialised in contentious matters, the Superior Court and the Supreme Court). Filing a lawsuit does not suspend the effects of the resolutions that are challenged. To do so, it is necessary to obtain a precautionary measure, but these are frequently rejected.

V FINANCIAL RELATIONSHIPS WITH PRESCRIBERS AND PAYERS

According to Article 31 of Law No. 29459, the prescription of medicines must necessarily include the INN, pharmaceutical form, dose, term of the treatment, form of administration and, optionally, the trade name. Not including the INN in the prescription is considered an administrative infringement and economic fines could be imposed.

Administrative Directive 208-MINSA/DIGEMID-V.01[5] is the legal norm that regulates the activities of medical representatives. According to this Directive, medical representatives should not encourage healthcare professionals to perform unethical prescription practices by offering, *inter alia*, courses, trips, rewards and presents. Travel and accommodation expenses are not prohibited but they should be granted in accordance with the ethical criteria for medicinal drug promotion approved by the World Health Organization. The

5 Approved by Ministerial Resolution No. 413-2015-MINSA on 1 July 2015.

Directive also prohibits the installation of stands, modules and offices at public or private health establishments. It is also not permitted for advertisements to be posted on the walls of medical offices.

Any support to healthcare professionals to participate in any domestic or international symposium should not be conditional upon any obligation to promote any pharmaceutical product and must be announced as a conflict of interest, when applicable.

VI SPECIAL LIABILITY OR COMPENSATION SYSTEMS

Under Peruvian law, product liability is ruled under the Consumer Protection Code (CPC) and the Civil Code. The CPC applies to any consumption relationship (relationships established between a consumer and a supplier, as defined below) entered into in the Peruvian territory or whose effects are performed therein. If the CPC is thus not applicable, then product liability shall be regulated by the Civil Code. General rules provide, however, that Peruvian law is applicable.

Consumers are defined as individuals or legal entities that purchase products as end users (i.e., not for business or professional activities). An individual or legal entity that purchases a product for business purposes shall not be considered a consumer. On the other hand, small businesses evidencing a situation of information asymmetry with the supplier in respect of certain products that are not part of their own course of business shall also be considered as consumers. By contrast, suppliers are defined as individuals or legal entities that regularly manufacture, process, handle, mix, pack, store, prepare, dispense or supply products of any kind to consumers. Suppliers may be, among others, distributors, producers or manufacturers, importers, or vendors.

Suppliers that cause damage to consumers with defective products are subject to strict liability and must pay compensation in accordance with the provisions of the Civil Code in the corresponding judicial process. When there are several suppliers of a product (e.g., manufacturer and distributor), they shall all be jointly liable. Notwithstanding the foregoing, each supplier has a right of recourse against the supplier that provided the defective product or caused the defect.

A supplier is also administratively liable for any breach of the CPC. The proceeding shall be conducted before the Consumer Protection Commission of Indecopi, which may impose fines of up to 1,867,500 soles and impose remedial and complementary corrective measures.

The Civil Code does not contain specific product liability rules. Nonetheless, general principles of civil liability contained in the Civil Code empower the victim of damage caused by a defective product to claim the corresponding compensation.

When there is no contractual relationship between seller and buyer (e.g., between the manufacturer and the end user), the seller may also be liable under tort liability. Article 1970 of the Civil Code provides that if a person causes damage to another person by means of a risky or dangerous product, or the exercise of a risky or dangerous activity, that person must compensate the victim of the damage. This article incorporates the strict liability principle in the Peruvian tort system, under which no degree of fault must be demonstrated. Peruvian scholarship argues that a defective product is a risky product and, therefore, when there is no contractual relationship between the seller and the buyer and the defective product causes damage to the buyer, the seller is subject to strict liability.

VII TRANSACTIONAL AND COMPETITION ISSUES

i Competition law

There are no specific competition regulations in Peru that apply exclusively to the pharmaceutical industry. However, there is a general Antitrust Law that promotes and protects free competition for all markets.

The regulations governing free competition are contained in Legislative Decree No. 1034 on the Repression of Anticompetitive Conducts (LRCA).

The authority in charge of enforcing the general legal framework governing free competition is Indecopi, which through its Commission on Free Competition, investigates and sanctions anticompetitive behaviour in the markets, with technical and functional autonomy.

Peruvian antitrust regulations apply to all practices that produce or may produce anticompetitive effects in all or part of the Peruvian territory, even if the practice originated abroad. The LRCA prohibits and sanctions three types of anticompetitive conduct, namely abuse of dominant position,[6] horizontal collusive practices[7] and vertical collusive practices.[8]

With regard to the nature of these prohibitions, some qualify as absolute prohibitions and others as relative prohibitions. According to Article 8 of the LRCA, the former refers to a behaviour that is forbidden *per se* and thus the competition agency will only have to prove the existence of the practice to determine the offence. However, in the case of relative prohibitions, to verify the existence of the offence, the existence of the practice must be proved and, additionally, it must be proved that it has or may have negative effects for competition and the well-being of consumers.

ii Transactional issues

There are no specific rules on transactional issues for pharmaceutical products and medical devices. Whether foreign laboratories are holders of the marketing authorisation of pharmaceutical products or medical devices must always be taken into account when analysing any transaction because there is always a dependence on the holder's will (usually local importers or drugstores companies that only have a commercial relationship with the laboratories) to transfer the marketing authorisation. Holders are even entitled to renounce the marketing authorisations and this could delay the commercialisation of products in the country as it would be necessary to obtain new marketing authorisations.

VIII CURRENT DEVELOPMENTS

In May 2018, the Ministry of Health published a draft of the Regulations of Law No. 30681 that regulates the production, importation and commercialisation of cannabis for medical

6 Holding a dominant position, with or without affecting real or potential competitors, does not constitute an illegal conduct. Monopolies or dominant position are not rejected *per se*, but rather the abusive use thereof.

7 Horizontal collusive practices imply the joint action of several competitors as if they were one. According to the LRCA, such practices may consist of concerted agreements, decisions, recommendations or practices among competitors with the aim or effect of restraining, preventing or forging competition.

8 These are collusive practices among economic agents operating at different levels of the production, distribution or marketing chain, aimed at restricting, preventing or forging free competition.

purposes. The Law is already effective but is inapplicable in practice without the Regulations. Although comments to the published draft Regulations were welcomed until August 2018, the draft has not yet been approved. It is expected that the Regulations will be enacted by mid 2019.

On 15 September 2018, Supreme Decree No. 024-2018-SA – Rules on interchangeability of medicines was enacted. It will become effective in March 2019, and intends to guarantee the efficacy, safety and quality of generic drugs (multi-source pharmaceutical products), provided that they prove to be therapeutic equivalents of the reference product.

Appendix 1

ABOUT THE AUTHORS

MARÍA DEL CARMEN ALVARADO BAYO

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María del Carmen Alvarado is a senior partner in the intellectual property department at Rodrigo, Elías & Medrano Abogados. She advises national and international investors on intellectual property, unfair competition, advertising, transfer of technology, franchising and life sciences. She is a former head of the Distinctive Signs Office at the National Institute for the Defence of Competition and Protection of Intellectual Property. She was also an international lawyer with Frito-Lay Inc in Dallas and president of the Peruvian Association of Industrial Property and Copyrights.

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